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from the new Surety for a term specified by the Medicaid agency.

(j) *Effect of failure to obtain, maintain, and timely file a surety bond.* (1) The Medicaid agency must terminate the HHA's provider agreement if the HHA fails to obtain, file timely, and maintain a surety bond in accordance with this section and the Medicaid agency's instructions.

(2) The Medicaid agency must refuse to enter into a provider agreement with an HHA if an HHA seeking to become a participating HHA fails to obtain and file timely a surety bond in accordance with this section and instructions issued by the State Medicaid agency.

(k) *Evidence of compliance.* (1) The Medicaid agency may at any time require an HHA to make a specific showing of being in compliance with the requirements of this section and may require the HHA to submit such additional evidence as the Medicaid agency considers sufficient to demonstrate the HHA's compliance.

(2) The Medicaid agency may terminate the HHA's provider agreement or refuse to enter into a provider agreement if an HHA fails to timely furnish sufficient evidence at the Medicaid agency's request to demonstrate compliance with the requirements of this section.

(l) *Surety's standing to appeal Medicaid determinations.* The Medicaid agency must establish procedures for granting appeal rights to Sureties.

(m) *Effect of conditions of payment.* If a Surety has paid the Medicaid agency an amount on the basis of liability incurred under a bond obtained by an HHA under this section, and the Medicaid agency subsequently collects from the HHA, in whole or in part, on such overpayment that was the basis for the Surety's liability, the Medicaid agency must reimburse the Surety such amount as the Medicaid agency collected from the HHA, up to the amount paid by the Surety to the Medicaid agency, provided the Surety has no other liability under the bond.

[63 FR 310, Jan. 5, 1998, as amended at 63 FR 10731, Mar. 4, 1998; 63 FR 29654, June 1, 1998; 63 FR 41170, July 31, 1998]

§441.17 Laboratory services.

(a) The plan must provide for payment of laboratory services as defined in §440.30 of this subchapter if provided by—

(1) An independent laboratory that meets the requirements for participation in the Medicare program found in §405.1316 of this chapter;

(2) A hospital-based laboratory that meets the requirements for participation in the Medicare program found in §482.27 of this chapter;

(3) A rural health clinic, as defined in §491.9 of this chapter; or

(4) A skilled nursing facility—based clinical laboratory, as defined in §405.1128(a) of this chapter.

(b) Except as provided under paragraph (c), if a laboratory or other entity is requesting payment under Medicaid for testing for the presence of the human immunodeficiency virus (HIV) antibody or for the isolation and identification of the HIV causative agent as described in §405.1316(f) (2) and (3) of this chapter, the laboratory records must contain the name and other identification of the person from whom the specimen was taken.

(c) An agency may choose to approve the use of alternative identifiers, in place of the requirement for patient's name, in paragraph (b) of this section for HIV antibody or causative agent testing of Medicaid recipients.

[54 FR 48647, Dec. 2, 1988. Redesignated at 63 FR 310, Jan. 5, 1998.]

§441.18 Case management services.

(a) If a State plan provides for case management services (including targeted case management services), as defined in §440.169 of this chapter, the State must meet the following requirements:

(1) Allow individuals the free choice of any qualified Medicaid provider within the specified geographic area identified in the plan when obtaining case management services, in accordance with §431.51 of this chapter, except as specified in paragraph (b) of this section.

(2) Not use case management (including targeted case management) services to restrict an individual's access to other services under the plan.

(3) Not compel an individual to receive case management services, condition receipt of case management (or targeted case management) services on the receipt of other Medicaid services, or condition receipt of other Medicaid services on receipt of case management (or targeted case management) services.

(4) Indicate in the plan that case management services provided in accordance with section 1915(g) of the Act will not duplicate payments made to public agencies or private entities under the State plan and other program authorities;

(5) [Reserved]

(6) Prohibit providers of case management services from exercising the agency's authority to authorize or deny the provision of other services under the plan.

(7) Require providers to maintain case records that document for all individuals receiving case management as follows:

(i) The name of the individual.

(ii) The dates of the case management services.

(iii) The name of the provider agency (if relevant) and the person providing the case management service.

(iv) The nature, content, units of the case management services received and whether goals specified in the care plan have been achieved.

(v) Whether the individual has declined services in the care plan.

(vi) The need for, and occurrences of, coordination with other case managers.

(vii) A timeline for obtaining needed services.

(viii) A timeline for reevaluation of the plan.

(8) Include a separate plan amendment for each group receiving case management services that includes the following:

(i) Defines the group (and any subgroups within the group) eligible to receive the case management services.

(ii) Identifies the geographic area to be served.

(iii) Describes the case management services furnished, including the types of monitoring.

(iv) Specifies the frequency of assessments and monitoring and provides a justification for those frequencies.

(v) Specifies provider qualifications that are reasonably related to the population being served and the case management services furnished.

(vi) [Reserved]

(vii) Specifies if case management services are being provided to Medicaid-eligible individuals who are in institutions (except individuals between ages 22 and 64 who are served in IMDs or individuals who are inmates of public institutions).

(9) Include a separate plan amendment for each subgroup within a group if any of the following differs among the subgroups:

(i) The case management services to be furnished;

(ii) The qualifications of case management providers; or

(iii) The methodology under which case management providers will be paid.

(b) If the State limits qualified providers of case management services for target groups of individuals with developmental disability or chronic mental illness, in accordance with § 431.51(a)(4) of this chapter, the plan must identify any limitations to be imposed on the providers and specify how these limitations enable providers to ensure that individuals within the target groups receive needed services.

(c) Case management does not include, and FFP is not available in expenditures for, services defined in § 441.169 of this chapter when the case management activities constitute the direct delivery of underlying medical, educational, social, or other services to which an eligible individual has been referred, including for foster care programs, services such as, but not limited to, the following:

(1) Research gathering and completion of documentation required by the foster care program.

(2) Assessing adoption placements.

(3) Recruiting or interviewing potential foster care parents.

(4) Serving legal papers.

(5) Home investigations.

(6) Providing transportation.

(7) Administering foster care subsidies.

(8) Making placement arrangements.

(d) After the State assesses whether the activities are within the scope of

the case management benefit (applying the limitations described above), in determining the allowable costs for case management (or targeted case management) services that are also furnished by another federally-funded program, the State must use cost allocation methodologies, consistent with OMB Circular A–87, CMS policies, or any subsequent guidance and reflected in an approved cost allocation plan.

[72 FR 68092, Dec. 4, 2007, as amended at 74 FR 31196, June 30, 2009]

§441.20 Family planning services.

For recipients eligible under the plan for family planning services, the plan must provide that each recipient is free from coercion or mental pressure and free to choose the method of family planning to be used.

§441.21 Nurse-midwife services.

If a State plan, under §440.210 or 440.220 of this subchapter, provides for nurse-midwife services, as defined in §440.165, the plan must provide that the nurse-midwife may enter into an independent provider agreement, without regard to whether the nurse-midwife is under the supervision of, or associated with, a physician or other health care provider.

[47 FR 21051, May 17, 1982]

§441.22 Nurse practitioner services.

With respect to nurse practitioner services that meet the definition of §440.166(a) and the requirements of either §440.166(b) or §440.166(c), the State plan must meet the following requirements:

(a) Provide that nurse practitioner services are furnished to the categorically needy.

(b) Specify whether those services are furnished to the medically needy.

(c) Provide that services furnished by a nurse practitioner, regardless of whether the nurse practitioner is under the supervision of, or associated with, a physician or other health care provider, may—

(1) Be reimbursed by the State Medicaid agency through an independent provider agreement between the State and the nurse practitioner; or

(2) Be paid through the employing provider.

[60 FR 19862, Apr. 21, 1995]

§441.25 Prohibition on FFP for certain prescribed drugs.

(a) FFP is not available in expenditures for the purchase or administration of any drug product that meets all of the following conditions:

(1) The drug product was approved by the Food and Drug Administration (FDA) before October 10, 1962.

(2) The drug product is available only through prescription.

(3) The drug product is the subject of a notice of opportunity for hearing issued under section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the FEDERAL REGISTER on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications.

(4) The drug product is presently not subject to a determination by FDA, made under its efficacy review program (see 21 CFR 310.6 for an explanation of this program), that there is a compelling justification of the drug product's medical need.

(b) FFP is not available in expenditures for the purchase or administration of any drug product that is identical, related, or similar, as defined in 21 CFR 310.6, to a drug product that meets the conditions of paragraph (a) of this section.

[46 FR 48554, Oct. 1, 1981]

§441.30 Optometric services.

The plan must provide for payment of optometric services as physician services, whether furnished by an optometrist or a physician, if—

(a) The plan does not provide for payment for services provided by an optometrist, except for eligibility determinations under §§435.531 and 436.531 of this subchapter, but did provide for those services at an earlier period; and

(b) The plan specifically provides that physicians' services include services an optometrist is legally authorized to perform.